IV. REMARKS

A. Status of the Application

Claims 1, 6, 9, 15-17, 22, 40 and 43 are currently amended. Claims 48-54 are added. Thus, claims 1, 6-17, 22, 27-36, 40-43 and 48-54 are now pending herein. Favorable consideration and allowance of claims 1, 6-17, 22, 27-36, 40-43 and 48-54 in view of the foregoing amendments and the following remarks are respectfully requested. Applicants' counsel wishes to thank the Examiner for the interview held on February 11, 2004.

B. Rejection Under 35 U.S.C. § 112, second paragraph

Claims 1, 6-17, 22, 27-36 and 40-43 stand rejected under 35 U.S.C. §112, second paragraph, for alleged indefiniteness. In particular, claims 1, 22 and 40 are alleged to be indefinite for recitation of the phrase "wherein said composition comprises predigested forms of said saccharides." Claims 6-17, 27-36 and 42-43 are rejected because of their direct or indirect dependency on claims 1, 22 or 40.

Claims 1, 22 and 40 have been amended to delete recitation of the objectionable phrase. Accordingly, Applicants respectfully request that the rejection of claims 1, 6-17, 22, 27-36 and 40-43 under 35 U.S.C. §112, second paragraph be withdrawn.

Applicants note that claim 40 was rejected only under 35 U.S.C. §112, second paragraph in the previous Office Action. Therefore, since the rejection of claim 40 under 35 U.S.C. §112, second paragraph has been overcome, claim 40 is in condition for allowance.

C. Rejections Under 35 U.S.C. § 102(b)

1. Claims 1, 6, 16 and 22 over Linscott and Remington.

Claims 1, 6, 16 and 22 stand rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 4,871,557 to Linscott (hereafter referred to as "Linscott '557"), and "as evidenced" by a publication by Remington et al. entitled *Breakfast, Invalid and Infant Food* (hereafter referred to as "Remington"). Applicants respectfully traverse this rejection on the grounds that neither Linscott '557 nor Remington meets the criteria necessary to sustain a rejection under 35 USC § 102(b).

As provided in MPEP § 2131, "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a *single* prior art reference." MPEP § 2131 at 2100-70 (emphasis added). As elaborated in *Richardson v. Suzuki Motor Co.*, "[t]he identical invention must be shown in as complete detail as is contained in the claim." 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1987). Further, to anticipate a claim, "a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter." *PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566, 37 U.S.P.Q.2d 1618, 1624 (Fed. Cir. 1996). Finally, as stated by the Courts in *Akzo N.V. v. ITC*, 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986) and *Titanium Metals Corp. v Banner*, 227 U.S.P.Q. 773, 778 (Fed. Cir. 1985), the anticipating prior art reference "must enable one skilled in the art to practice the claimed invention, thus placing the allegedly disclosed matter in the possession of the public." Therefore, in order to anticipate the claims of the present invention, Linscott '557 or Remington must disclose each and every element of claims 1, 6, 16 and 22 to sustain this rejection and enable the skilled artisan to make the anticipated subject matter.

Linscott '557 merely discloses a granola bar with whole supplemental fiber such as apple pectin, gum arabic, gum ghatti and guar gum. The fibers taught by Linscott '577 are made of "undigestible fiber," intended to provide, and limited to, "dietary fiber" which the '577 specification clearly defines in the Background of the Invention as "indigenous components of plant materials in the diet which are *resistant to digestion by enzymes produced by humans*." Col. 1, ll. 10-13 (emphasis added). As such, the Linscott '557 reference could never provide "expressly or inherently" the "nutritionally effective amounts" of any "isolated and purified" saccharides as claimed by the present invention. Therefore, Linscott '557 fails the test set-forth in MPEP § 2131 as it does not provide "each and every element as set forth in the claim," specifically saccharides that are nutritionally effective. Evidence of Linscott's failure to anticipate the present claims is also found in the present record in the form of the Declarations of Boyd, Gardiner and Murray, which specifically address the proper scope and limitations of Linscott.

Likewise, Remington merely discloses cooking raw cereals, a process which does not provide nutritionally effective amounts of isolated and purified saccharides that are available to the host of the present invention, as provided by the evidence presented by the Applicants in the

three Declarations submitted previously.. In fact, even after the "treatment" afforded the fibers in Remington, Remington acknowledges that the "cell walls have not been broken to any great extent in the milling process," thereby requiring additional cooking. Remington, page 155, Col. 2, line 18-20. Even after cooking the grains, Remington does not teach how to isolate and purify any saccharides that are available to the host in a "nutritionally effective amount." In addition, Remington discloses on page 155, column 2, line 23 to page 156, column 1, line 23, that rolled and flaky preparations of cereals contain soluble *starch*, not soluble *saccharide*. (see also, Col. 1, examples listed (i) to (vi)).

In contrast, claim 1 as amended is drawn to a dietary supplement composition comprising "a nutritionally effective amount" of "each of at least six isolated and purified saccharides." Neither Linscott, nor Remington, alone or in combination provide any teaching of either "nutritionally effective amount" or of "isolated and purified" saccharides. The reason is that they simply can not. Linscott only teaches providing a Granola Bar that provides "dietary fiber" which is inherently undigestible by humans. The undigestible fiber of Linscott is not an "isolated and purified" saccharide in a composition, as claimed herein, nor could it be as the fibers are indigestible and therefore not available in any nutritionally effective amount to a host. Linscott can not provide "a nutritionally effective" of "each of at least six saccharides" because: (1) it teaches no "nutritional supplement;" (2) it teaches no way to achieve a nutritional supplement; (3) it teaches no way to isolate saccharides; and (4) it teaches no way to purify saccharides, much less make them available to a host.

In sharp contrast, the present invention as claimed is directed to exactly that, providing "nutritional supplementation" in the form of isolated and purified saccharides that are available to the host, e.g., as the building blocks of glycoproteins. Linscott fails to anticipate any combination of nutritionally effective, isolated and purified saccharides because it does not teach, disclose or enable how to attain those individual "nutritionally effective" saccharides, it does not teach how to mix them or even hint at the benefits of such nutritional supplementation. Nor does Linscott provide any examples of nutritionally effective saccharides such as isolated and purified galactose, glucose, mannose, xylose and acetylated mannose. Linscott does not teach, e.g., acetylated mannose because none of the dietary fibers that it uses as a source of fiber even includes acetylated mannose.

As such, neither reference discloses or suggests each and every element of claim 1, therefore the present rejection of claim 1 under 35 U.S.C. § 102(b) fails. Moreover, the present rejection over Linscott '557 and Remington of claims 6 and 16, each of which depends from claim 1, cannot be maintained for at least the same reasons as claim 1.

Further still, neither Linscott '557, nor Remington discloses or suggests each and every element of claim 22. Claim 22 as amended is drawn to a dietary supplement composition that comprises a "nutritionally effective amount" of "each of at least six isolated and purified saccharides," wherein at least a first one of the six isolated and purified saccharides is selected from a first group of saccharides consisting of: galactose, glucose, mannose and xylose. At least a second one of the six isolated and purified saccharides is selected from a second group of saccharides consisting of: N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, arabinose, glucuronic acid and iduronic acid. The first one of the six isolated and purified saccharides comprises from about 0.1 to about 75 weight percent of the composition, and the second one of the six isolated and purified saccharides comprises from about 0.1 to about 75 weight percent of the composition.

Neither Linscott '557 nor Remington discloses or suggests a dietary supplement composition comprising a "nutritionally effective amount" of each of at least six isolated and purified saccharides as described in claim 22. In particular, neither reference discloses or suggests a dietary supplement composition comprised of from about 0.1 to about 75 weight percent of each of at least six saccharides that are isolated and purified and selected from the two lists provided.

For the foregoing reasons, it is respectfully requested that the rejection of claims 1, 6, 16 and 22 over Linscott '557 and Remington be withdrawn.

2. Claims 1, 6 and 22 over Bartolome, Kato and Beldman.

Claims 1, 6 and 22 stand rejected under 35 USC § 102(b) over a publication by Bartolome et al. entitled *Polysaccharides from the cell walls of pineapple fruit* (hereafter referred to as "Bartolome"), a publication by Kato et al. entitled *Hydrolyzate of soybean hull prepared by using cellulose* (hereafter referred to as "Kato"), and a publication by Beldman et al. entitled *Enzymic hydrolysis of beer brewer's spent grain and the influence of pretreatments* (hereafter

referred to as "Beldman"). Applicants respectfully traverse this rejection on the grounds that none of Bartolome, Kato or Beldman meets the criteria necessary to sustain a rejection under 35 USC § 102(b).

As provided in MPEP § 2131, the standard for claim anticipation is that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a *single* prior art reference." MPEP §2131 at 2100-70 (emphasis added). This standard is not met in the present case as none of Bartolome, Kato or Beldman discloses each and every element of claims 1, 6 and 22.

Bartolome merely discloses extracting cell wall material from a pineapple with 4M KOH, and isolating a "neutral" polysaccharide therefrom. The "neutral" polysaccharide fraction allegedly consisted of xylose, arabinose, glucose, galactose and minor quantities of mannose. While it is at best arguable that to some extent the cell wall extract is isolated and purified, it is clearly not isolated and purified to the extent that it can also be provided in a nutritionally effective amount. Bartolome is merely an analysis of what is in the cell wall, and does not teach or enable the production of the nutritional supplement of the claimed invention. Bartolome is merely scientific inquiry, i.e., "what is there", and does not attempt to provide a host with isolated and purified saccharides in nutritionally effective amounts as needed by a host. Thus, dietary supplementation with available isolated and purified saccharides provided to a host in nutritionally effective amounts is taught disclosed or suggested by Bartolome. Furthermore, Bartolome falls outside the field of endeavor and is not reasonably pertinent to the problem solved.

The English language abstract of Kato discloses, at best, that soybean hull was hydrolyzed by the cellulase of trichoderma and the hydrolyzate was used to produce soy sauce. A solution obtained by treating soybean hull koji with the cellulase of trichoderma was found to include rhamnose, xylose, arabinose, glucose, cellobiose and dextrin.

Finally, Beldman discloses the enzymatic hydrolysis of spent grain by commercial cellulases. However, Applicants' note that Beldman discloses on page 669, Table 3, that the sugar composition of spent grains after 2.0 N sulfuric acid hydrolysis included varying amounts of arabinose, xylose, mannose, galactose and glucose, depending upon subsequent treatment either by drying, extraction with ethanol or extraction with water. While Table 3 includes a line

item for rhamnose and fucose, the table discloses that the amount of such sugars in the various compositions is 0%. Moreover, enzymatic hydrolysis of spent grain by commercial cellulases according to Beldman resulted in a range of polysaccharide hydrolysis from 41-47%.

First and foremost, none of these references provide any teaching or enablement of a "nutritionally effective amount" of anything, much less of a nutritional supplement that provides isolated and purified saccharides that are available to the host. There is no teaching of the preparation of any supplement. In fact, the use of harsh hydrolysis (e.g., 2.0 N sulfuric acid) and treatment with strong bases (4 M KOH) strongly militate against the use of any remaining saccharides for anything other than simple, mere characterization. Nor does enzymatic treatment with cellulases from a pathogen such as trichoderma teach the preparation of a nutritionally effective amount of the saccharides claimed herein. Quite to the contrary, these are references that merely characterize components without any indication, teaching, suggestion, enablement or motivation that any of the saccharides that may be contained may be prepared into a dietary supplement. Furthermore, none of the references provide any teaching or enablement for modifying the content of the saccharides to provide "a nutritionally effective amount."

In contrast, claim 1 as amended is drawn to a dietary supplement composition comprising a "nutritionally effective amount" of each of at least six isolated and purified saccharides. At least one of the six isolated and purified saccharides is selected from a first group of saccharides consisting of: galactose, glucose, mannose, xylose and acetylated mannose, and at least one of the six isolated and purified saccharides is selected from a second group of saccharides consisting of: N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, arabinose, glucuronic acid, galacturonic acid, iduronic acid and arabinogalactan.

None of Bartolome, Kato or Beldman discloses or suggests a dietary supplement composition comprising a nutritionally effective amount of each of at least six isolated and purified saccharides as described in claim 1. As neither reference discloses or suggests each and every element of claim 1, the present rejection of claim 1 under 35 USC § 102(b) cannot be maintained. Moreover, the present rejection over Bartolome, Kato or Beldman of claim 6, which depends from claim 1, cannot be maintained for at least the same reasons as noted above with respect to claim 1.

Further still, none of Bartolome, Kato or Beldman discloses or suggests each and every element of claim 22. Claim 22 as amended is drawn to a dietary supplement composition comprising a nutritionally effective amount of each of at least six isolated and purified saccharides. At least a first one of the six isolated and purified saccharides is selected from a first group of saccharides consisting of: galactose, glucose, mannose and xylose. At least a second one of the six isolated and purified saccharides is selected from a second group of saccharides consisting of: N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, arabinose, glucuronic acid and iduronic acid. The first one of the six isolated and purified saccharides comprises from about 0.1 to about 75 weight percent of said composition, and the second one of the six isolated and purified saccharides comprises from about 0.1 to about 75 weight percent of said composition.

None of Bartolome, Kato or Beldman discloses or suggests a dietary supplement composition comprising a nutritionally effective amount of each of at least six isolated and purified saccharides as described in claim 22. Moreover, none of Bartolome, Kato or Beldman discloses or suggests a dietary supplement composition comprised of from about 0.1 to about 75 weight percent of a first and second isolated and purified saccharide.

For the foregoing reasons, it is respectfully requested that the rejection of claims 1, 6 and 22 over Bartolome, Kato and Beldman be withdrawn.

3. Claims 1 and 6 over Beran.

Claims 1 and 6 stand rejected under 35 USC § 102(b) over a publication by Beran et al. entitled *Saccharification of starch in potato mash with fungus amylolytic preparations* (hereafter referred to as "Beran").

The English language abstract of Beran discloses a potato mash extract that has been saccharified with aspergillus niger or a combination of aspergillus niger and aspergillus oryzae. The potato mash extract is disclosed to contain fructose, galactose, glucose, maltose, maltotriose, isomaltose, panose, nonidentified pentoses and galacturonic acid. Again, none of modification, isolation and purification of the saccharides is provided by Beran that would allow a dietary supplement to be prepared that is "nutritionally effective." Moreover, Beran does not have a teaching or enabling disclosure that saccharides could be made available to a host and provided

to a host for glyconutritional supplementation. In fact, the reference fails to teach how the enzymes from these potential pathogens would be removed to provide such a nutritional effective amount to a host.

In contrast, claim 1 as amended is drawn to a dietary supplement composition comprising a nutritionally effective amount of each of at least six isolated and purified saccharides. At least one of the six isolated and purified saccharides is selected from a first group of saccharides consisting of: galactose, glucose, mannose, xylose and acetylated mannose. At least one of the six isolated and purified saccharides is selected from a second group of saccharides consisting of: N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, arabinose, glucuronic acid, galacturonic acid, iduronic acid and arabinogalactan.

Beran fails to anticipate the claimed invention because Beran does not disclose, enable or suggest a dietary supplement composition comprising a nutritionally effective amount of each of at least six isolated and purified saccharides as described in claim 1. As Beran does not disclose or suggest each and every element of claim 1, the present rejection of claim 1 under 35 USC § 102(b) cannot be maintained. Moreover, the present rejection over Beran of claim 6, which depends from claim 1, cannot be maintained for at least the same reasons as noted with respect to claim 1.

For the foregoing reasons, it is respectfully requested that the rejection of claims 1 and 6 over Beran be withdrawn.

D. Rejections Under 35 U.S.C. § 103(a)

1. Claims 1, 6, 7, 16 and 27-30 over Linscott in view of Cayen and Pegel.

Claims 1, 6, 7, 16, and 27-30 stand rejected under 35 USC §103(a) over Linscott '557 in view of U.S. Patent No. 3,890,438 to Cayen et al. (hereafter Cayen '438) and U.S. Patent No. 4,260,603 to Pegel et al. (hereafter Pegel '603). Insofar as it may be applied against the present claims, this rejection is respectfully traversed.

Linscott '557 discloses a granola bar with supplemental fiber such as apple pectin, gum arabic, gum ghatti and guar gum.

Cayen '438 discloses pharmaceutical compositions for lowering blood cholesterol that include a mixture of diosgenin or a related diosgenin derivative and a 4-substituted

phenoxyisobutryic acid or an ester or salt thereof. Cayen '438 discloses that suitable pharmaceutical formulations include tablets comprising: (a) the above-noted compositions, (b) known pharmaceutical carriers and excipients such as starch, sugars and lubricants, suspensions or syrups comprising the above-noted compositions, and (c) suspending agents such as water soluble gums.

Pegel '603 discloses a medicament having prostaglandin-synthetase inhibiting activity. The medicament is disclosed to contain as an active principle sterolglycosides and/or their esters and/or spiroketal steroid glycosides and/or esters thereof.

As provided in MPEP § 2143, "[t]o establish a prima facie case of obviousness ... the prior art reference (or references when combined) must teach or suggest all the claim limitations." Furthermore, under MPEP § 2142, "[i]f the examiner does not produce a prima facie case, the applicant is under no obligation to submit evidence of nonobviousness." It is submitted that the Office action does not factually support a prima facie case of obviousness based on Linscott '557, Cayen '438 and Pegel '603 for the following reasons.

A prerequisite to making a finding of Section 103 obviousness is determining what is "prior art," in order to consider whether the differences between the subject matter to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art. *In re Clay*, 966 F.2d 656, 23 U.S.P.Q. 1058 (Fed. Cir. 1992). If a cited reference "is not analogous art it has no bearing on the obviousness of the patent claim." *Jurgens v. McKasy*, 927 F.2d 1552, 18 U.S.P.Q. 1031 (Fed. Cir.), cert den'd, 502 U.S. 902 (1991). Under the two-step test for determining whether a prior art reference is non-analogous and thus not relevant in determining obviousness, one must determine: (1) whether the reference is "within the field of the inventor's endeavor;" and (2) if not, whether the reference is "reasonably pertinent to the particular problem with which the inventor was involved." *In re Deminski*, 796 F.2d 436, 230 U.S.P.Q. 313 (Fed. Cir. 1986). The purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve. If the purpose of the invention is directed to a different purpose, the inventor would accordingly have had less motivation or occasion to consider it. *In re Clay*, 966 F.2d 656 (Fed. Cir. 1992).

As discussed above with respect to the rejection of claims 1, 6, 16 and 22 under 35 USC §102(b), which discussion in incorporated herein by reference, Linscott '557 does not disclose or suggest the subject matter of claim 1. Specifically, Linscott '557 does not disclose or suggest a dietary supplement composition comprising a nutritionally effective amount of each of at least six isolated and purified saccharides as described in claim 1.

Therefore, since claims 6, 7, 16 and 17-30 depend directly or indirectly from claim 1, Linscott '557 does not disclose or suggest the subject matter of claims 6, 7, 16, and 27-30.

Neither Cayen '438 nor Pegel '603 supplies the deficiencies of Linscott '557 with respect to claims 1, 6, 7, 16, and 27-30. Nor do any of the references teach, suggest or motivate any such combination. The examiner is earnestly requested to provide evidence on the record in the cited references of any such suggestion or motivation or withdraw the rejection. Thus, the combination of Cayen '438 and Pegel '603 with Linscott '557 fails to meet the standard presented by MPEP § 2143 which, as stated above, requires that the combined prior art references must teach or suggest all the claim limitations to establish a prima facie case of obviousness.

Furthermore, MPEP § 2143.01 provides that "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." Linscott '557 is directed to a granola bar with supplemental dietary fiber. Cayen '438 is directed to compositions for reducing blood cholesterol. Pegel '603 is directed to a sterol glycoside with activity as a prostaglandin synthetase inhibitor. Each reference addresses a different matter and one of ordinary skill in the art would have no reason or motivation to combine any of such references, much less all three of them. Therefore, there is no basis for the combination of Linscott '557, Cayen '438 and Pegel '603, and it is respectfully submitted that the combination is improper.

For the foregoing reasons, it is respectfully requested that the rejection of claims 1, 6, 7, 16, and 27-30 under 35 USC § 103(a) over Linscott '557 in view of Cayen '438 and Pegel '603 be withdrawn.

2. Claims 1, 6-17 and 27-36 over Linscott, Cayen and Pegel, in view of Graves, Balch, Policappelli, Morrison and Dohnalek.

Claims 1, 6-17 and 27-36 stand rejected under 35 USC §103(a) over Linscott '557, Cayen '438 and Pegel '603, in view of U.S. Patent No. 5,202,122 to Graves (hereafter Graves '122), *Prescription For Nutritional Healing* by Balch et al. (hereafter Balch), U.S. Patent No. 5,612,039 to Policappelli et al. (hereafter Policappelli '039), U.S. Patent No. 4,466,958 to Morrison (hereafter Morrison '958) and U.S. Patent No. 5,827,526 to Dohnalek et al. (hereafter Dohnalek '526). Insofar as it may be applied against the present claims, this rejection is respectfully traversed.

The disclosures of Linscott '557, Cayen '438 and Pegel '603 are discussed above, which discussions are incorporated herein by reference.

Graves '122 discloses a process for enhancing the natural bile acid binding capacity of edible pulp material, which is also referred to as dietary fiber. Graves '122 merely discloses that the major constituents of dietary fiber include cellulose, hemicellulose, lignin and pectin. Graves '122 also discloses at column 6, lines 37-42 that pectin comprises the neutral sugars D-galactose, L-arabinose, D-xylose and L-fucose.

Balch appears to be a general guide to the bodily function and source of a multitude of vitamins, herbs and food supplements. Balch indeed discloses that vitamins are essential to life and that every living cell on the planet depends on minerals for proper function and structure. However, Balch does not disclose or suggest a dietary supplement composition that includes at least six saccharides in which the saccharides are available as monosaccharides.

Policappelli '039 discloses a dietary supplement composition that includes herbal extracts combined with glucomannan or galactomannan.

Morrison '958 discloses a food supplement that includes soy lecithin.

Dohnalek '526 discloses the use of fructooligosaccharides that occur in plants such as onions, asparagus, and tomatoes to prevent gastrointestinal infections and to reduce duration of diarrhea in humans.

As provided in MPEP § 2143, "[t]o establish a prima facie case of obviousness ... the prior art reference (or references when combined) must teach or suggest all the claim limitations." Furthermore, under MPEP § 2142, "[i]f the examiner does not produce a prima

facie case, the applicant is under no obligation to submit evidence of nonobviousness." It is submitted that the Office action does not factually support a prima facie case of obviousness based on Linscott '557, Cayen '438, Pegel '603, Graves '122, Balch, Policappelli '039, Morrison '958 and Dohnalek '526 for the following reasons.

As discussed above with respect to the rejection of claims 1, 6, 7, 16 and 27-30 under 35 USC § 103(a), which discussions are incorporated in full herein by reference, Linscott '557, Cayen '438 and Pegel '603 do not disclose or suggest the subject matter of claim 1. Specifically, none of Linscott '557, Cayen '438 or Pegel '603 disclose or suggest a dietary supplement composition comprising a nutritionally effective amount of each of at least six isolated and purified saccharides as described in claim 1.

Therefore, since claims 6-17 and 27-36 depend directly or indirectly from claim 1, none of, Linscott '557, Cayen '438 or Pegel '603 disclose or suggest the subject matter of claims 6-17 and 27-36.

None of Graves '122, Balch, Policappelli '039, Morrison '958 and Dohnalek '526 supply the deficiencies of Linscott '557, Cayen '438 or Pegel '603 with respect to claims 1, 6-17, 22 and 27-36. Thus, the combination of Graves '122, Balch, Policappelli '039, Morrison '958 and Dohnalek '526 with Linscott '557, Cayen '438 and Pegel '603 fails to meet the standard presented by MPEP § 2143 which, as stated above, requires that the combined prior art references must teach or suggest all the claim limitations to establish a prima facie case of obviousness.

Furthermore, MPEP § 2143.01 provides that "[t]he mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." The cited art provides no such suggestion.

Linscott '557 is directed to a granola bar with supplemental dietary fiber. Cayen '438 is directed to compositions for reducing blood cholesterol. Pegel '603 is directed to a sterol glycoside with activity as a prostaglandin synthetase inhibitor. Graves '122 is directed to a process for enhancing the natural bile acid binding capacity of edible pulp material. Balch is a general guide to the bodily function and source of a multitude of vitamins, herbs and food supplements. Policappelli '039 is directed to a dietary supplement composition that includes herbal extracts combined with glucomannan or galactomannan. Morrison '958 is directed to a

food supplement that includes soy lecithin. Dohnalek '526 is directed to the use of fructooligosaccharides that occur in plants such as onions, asparagus, and tomatoes to prevent gastrointestinal infections and to reduce duration of diarrhea in humans.

Each reference addresses a different matter, and one of ordinary skill in the art would have no reason or motivation to combine any of such references, much less all nine of them. The references contain no suggestion for their combination, and the present Office Action is devoid of any evidence showing such suggestion. Therefore, there is no basis for the combination of Linscott '557, Cayen '438, Pegel '603, Graves '122, Balch, Policappelli '039, Morrison '958 and Dohnalek '526, and it is respectfully submitted that the combination is improper.

At most, the cited references establish that it might be "obvious to try" various combinations of ingredients. However, "obvious to try" is not the standard for patentability under 35 U.S.C. § 103. The Federal Circuit has stated:

> In some cases, what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were crucial or no direction as to which of many possible choices is likely to be successful. [citing cases]
>
> ... In others, what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the invention or how to achieve it.

In re O'Farrell, 7 U.S.P.Q.2d 1673, 1681 (Fed. Cir. 1988). Both "obvious to try" situations arise here. The Examiner has cited patents and references with disclosures too broad to render Applicants' specific combination of ingredients obvious, and has proposed a modification to one or more of the ingredients based only on, at best, a very generalized motivation of seeking a dietary supplement. Furthermore, even if the components are as interchangeable as the examiner maintains, the cited prior art does not give rise to the reasonable expectation of success required by *In re O'Farrell*, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) and *In re Dow Chemical*, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988), as there is no teaching that any such "nutritionally effective amounts" have been prepared and/or provided to obtain a dietary supplement of the listed isolated and purified saccharides.

For the foregoing reasons, it is respectfully requested that the rejection of Claims 1, 6-17, 22 and 27-36 under 35 USC § 103(a) over Linscott '557, Cayen '438 and Pegel '603 in view of Graves '122, Balch, Policappelli '039, Morrison '958 and Dohnalek '526 be withdrawn.

E. New claims 48-54

Each of new claims 48-54 depends directly or indirectly from claim 40. Claim 40 as amended herein is drawn to a dietary supplement composition comprising a nutritionally effective amount of isolated and purified galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose.

Applicants submit that none of the art cited in the present Office Action is sufficient to support a rejection of claims 40 and 48-54 under 35 USC § 102(b) or §103(a). Accordingly, Applicants respectfully request the allowance of new claims 48-54.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that claims 1, 6-17, 22, 27-36, 40-43 and 48-54 are in condition for allowance. Favorable reconsideration and allowance of claims 1, 6-17, 22, 27-36, 40-43 and 48-54 are respectfully requested.

Respectfully submitted,

Date: 3/10/04

Randall C. Brown
Registration No. 31,213
Attorney for Applicants

HAYNES AND BOONE, L.L.P.
901 Main Street, Suite 3100
Dallas, Texas 75202-3789
Tel: (214) 651-5242
Fax: (214) 200-0853